

**REMARKS**

The subject invention relates to a method of skin tightening that includes generating broadband light and filtering that light to produce a spectrum having a wavelength band principally between 1050nm and 1850nm. The light is directed to the tissue through a cooled transmissive material that is placed in contact with the skin. The treatment period lasts between approximately 1.2 to 5 seconds and heats a volume of the dermis at a depth between 1mm and 5mm to a treatment temperature at least 50°C while maintaining the upper regions of the dermis at a temperature below the treatment temperature.

In the previous Office Actions, the Examiner has rejected claims 15 to 17, 22, 33, 42 and 43 as being unpatentable over Anderson (U.S. 6,120,497) in view of Altshuler ('3042) and Altshuler ('3780).

Applicants' previous response included a detailed declaration from Dr. Macrene Alexiades-Armenakas. Dr. Alexiades was selected because she is a person highly skilled in the art of dermatology and skin tightening treatments. She has performed clinical studies on skin tightening using virtually every new commercially introduced product including the assignee's Titan device which operates in accordance with the parameters set forth in claim 15 of the subject application.

The Alexiades Declaration discussed in detail why she believed that the prior art as applied by the Examiner failed to teach or suggest the inventions covered in the pending claims. In the Final Office Action, the Examiner raised certain issues with respect to some of the statements set forth in Dr. Alexiades' Declaration. In response, Applicants have submitted a supplemental declaration from Dr. Alexiades ("Alexiades Supplemental Declaration") intended to address the Examiner's remaining concerns. It is believed that if the Examiner fully considers the concepts set forth in the Alexiades Supplemental Declaration, he will recognize the deficiencies of the cited prior art.

As there has been a lengthy prosecution to date, Applicants will focus solely on what is believed to be the open issues. More particularly, in the Office Action, the Examiner broadly relies on Anderson for its teaching of using radiation to shrink collagen. The Examiner also suggests that Anderson teaches using a band of wavelengths between 1.3 microns and 1.8 microns. Finally, at page 4 of the Office Action, the Examiner argues that Anderson teaches a treatment time between 2

and 40 seconds. The reference to the treatment times in Anderson at page 4 of the Office Action should be contrasted with the discussion at page 6 of the Office Action wherein the Examiner relies on the teachings in Altshuler '3042 for its disclosure of a treatment time of 2 seconds to 2 hours to render obvious the claimed treatment time of 1.2 to 5 seconds.

The Examiner also relies on Altshuler '3042 for its teaching of a variety of wavelength ranges for treating tissue for rendering obvious Applicants claimed range of 1050nm to 1850nm. Each of these issues has been addressed in the Alexiades Supplemental Declaration and will be discussed below.

For completeness, the Examiner relies on Altshuler '3780 for its teaching of cooling tissue in conjunction with the application of the treatment radiation. Applicants are not challenging this aspect of the rejection.

As noted above, Anderson was cited for its teaching of shrinking collagen by applying optical radiation. Anderson teaches that his method can be implemented using a laser generating a single, narrowband wavelength. In fact, Anderson gives specific examples of particular lasers that would generate light having a wavelength in the desired range between 1.3 and 1.8 microns. Anderson also teaches that a light source that generates incoherent radiation could be used. Anderson teaches that if an incoherent light source is used, the power density should be between 5 watts and 100 watts per square centimeter. Beyond that, Anderson provides no further guidance on using an incoherent light source for treatment.

In her original Declaration, Dr. Alexiades opined that taken as a whole, Anderson failed to teach the concept of treating the tissue with broadband light. In the Final Office Action, the Examiner felt that Anderson at least taught using a "wavelength band." From a physics standpoint, it would be expected that a filtered, incoherent light source would generate a "wavelength band" that would have a bandwidth larger than the very narrow bandwidth generated by the types of solid state lasers discussed in the Anderson patent. Applicants would not dispute this interpretation of Anderson. However, Applicants would dispute any suggestion that Anderson teaches treating the tissue with a broadband radiation, and particularly broadband light spanning the 1.3 to 1.8 micron range.

As set forth in the Alexiades Supplemental Declaration, one skilled in the art would not interpret Anderson in that fashion. In particular, Dr. Alexiades notes that throughout the entire patent, Anderson refers to the treatment radiation as having “a” wavelength or “the” wavelength. Even the claims of the Anderson patent are limited to generating a beam of radiation having “a” wavelength between 1.3 and 1.8 microns. If Anderson intended to teach a treatment method that utilized broadband radiation, he would not have written his claims to refer to a beam having “a” wavelength. (Alexiades Supplemental Declaration ¶¶ 5 to 7) In view of the above, and in conjunction with the opinion of one highly skilled in the art, it is submitted that Anderson fails to teach treating tissue with broadband radiation. The failure of Anderson to teach treatment with broadband radiation undermines the Examiner’s prima facie case of obviousness.

In the Office Action on page 4, the Examiner argued that Anderson effectively teaches a treatment time interval between 2 and 40 seconds. To reach this conclusion, the Examiner notes that Anderson teaches the “application of 10-150 joules of energy using 5-100 watts of power.” The Examiner then argues that this “would require a treatment time of between 40 seconds (150 joules at 100 Watts) and 2 seconds (10 joules at 5 Watts).” The calculation proposed by the Examiner is based on misreading of Anderson. In fact, Anderson states that laser radiation has a “fluence” of between 10 and 150 joules, not an energy of 10 to 150 joules. As noted by Dr. Alexiades, “One skilled in the art would understand that fluence relates to the energy applied over a given area (typically  $\text{cm}^2$ ). One cannot calculate a treatment time given only fluence and power.” (Alexiades Supplemental Declaration ¶¶ 8 and 9) Accordingly, Anderson fails to teach a treatment time of between 2 and 40 seconds.

As previously discussed, Altshuler ‘3042 relates to treating tissue with optical radiation. Altshuler purports to be disclosing methods that are applicable to dozens of different treatment targets. Paragraphs 28, 29, and 30 of Altshuler ‘3042 list treatments ranging from pain relief to spinal cord problems to carpal tunnel syndrome to cancer therapy. Altshuler lists dozens of different treatment protocols and wavelength ranges. As noted by Dr. Alexiades, the disclosure in Altshuler contains “a large catalogue of possible treatment concepts with a relatively small amount of concrete teachings that would be necessary to effectively carry out specific procedures.” (Alexiades Supplemental Declaration ¶11) The listing of so many treatment types and so many

different wavelength ranges is merely an invitation to begin experimenting to find the best treatment parameters for a particular procedure.

As noted previously, despite the many different wavelength ranges disclosed in Altshuler, none come close to the claimed range of 1050nm to 1850nm. Further, none of the specified ranges are tied to skin tightening. As noted by Dr. Alexiades, "There is no rationale disclosed in Altshuler that would allow one skilled in the art to determine the optimum wavelength range for skin tightening." For these reasons, Dr. Alexiades concludes that "One skilled in the art would simply not find the claimed range of 1050nm to 1850nm for skin tightening to be taught or suggested based on Altshuler's scattershot disclosure." (Alexiades Supplemental Declaration ¶12)

In the Final Office Action, the Examiner questioned how Altshuler's inclusion of shorter wavelength radiation in the treatment radiation, i.e., below 1050nm, would "negate the efficacy" of the upper ranges of the applied wavelengths. The reason these shorter wavelengths would negate the efficacy of the longer wavelengths was initially discussed in Dr. Alexiades first declaration at paragraph 12. Specifically, "Wavelengths spanning 800-1000 nm result in much vascular and pigment absorption, limiting the fluence and number of passes one can safely administer, and thereby preventing adequate heat deposition into deeper dermis." This explanation is expanded in the Supplemental Declaration as follows:

In the Final Office Action, the Examiner questioned how including shorter wavelength radiation in the treatment radiation, i.e., below 1050nm, would "negate the efficacy" of the upper ranges of the applied wavelengths. The reason these shorter wavelengths would negate the efficacy of the longer wavelengths is that the shorter wavelengths are highly absorbed in the melanosomes and hemoglobin located in the upper layers of the skin. This will result in a high level of absorption of these shorter wavelengths in these superficial targets generating heat in the superficial layers including the epidermis, dermo-epidermal junction and the papillary blood vessels, greatly limiting the ability to deliver higher fluences to the lower depths and larger targets required for a skin tightening procedure. Based on my experience, the wavelength ranges suggested by Altshuler that include the 800nm to 1050nm range or the 900nm to 1050nm range will not work well because either (a) not enough fluence will be delivered to the lower depths or (b) assuming the power were increased to obtain the necessary fluence to treat the tissue at the lower depths, the upper levels of the patient's skin, e.g. epidermis, dermo-epidermal junction, and papillary blood vessels, would be heated too much, causing pain, potential burns and potential vascular necrosis. (Alexiades Supplemental Declaration ¶13)

Thus, it can be seen that the shorter wavelengths proposed by Altshuler would render his claimed method unworkable to effectively tighten the skin.

In the Office Action, the Examiner also noted that Altshuler proposed using a wavelength range of 1100nm to 1250nm that falls within the claimed range. As noted above, Altshuler fails to tie this range to skin tightening among his dozens of other suggested treatments. This is not surprising since this range would not work for skin tightening. As noted by Dr. Alexiades, “This narrow wavelength band has high absorption in the sebaceous glands, making it extremely difficult to deliver enough energy to the collagen and other dermal targets necessary to obtain the desired result. In my opinion, in order to obtain satisfactory results, the treatment radiation should include a broad-band of wavelengths, including those above 1250nm and preferably up to about 1850nm.”

(Alexiades Supplemental Declaration ¶14)

Accordingly, the general disclosure by Altshuler of using 1100nm to 1250nm to treat tissue fails to render obvious the method of applying broadband radiation having a range between 1050nm to 1850nm to achieve skin tightening.

Claim 15 also specifies a treatment time of 1.2 to 5 seconds. This treatment time is not taught in either Anderson or Altshuler. As noted above, the Examiner’s reliance on Anderson is technically in error. Altshuler’s teachings with respect to treatment intervals are no more useful than his teachings related to wavelength ranges. Telling one skilled in the art that the treatment time should be between 2 seconds and 2 hours is akin to telling her nothing at all. Certainly, a treatment time interval for skin tightening of between 1.2 and 5 seconds is not obvious from this teaching.

(Alexiades Supplemental Declaration ¶16)

In the Office Action, the Examiner appears to believe determining a treatment time is a trivial exercise. Dr. Alexiades has stated that this is not correct. She explains her reasoning in more detail in her Supplemental Declaration as follows:

[I]t is not so easy to accurately determine tissue temperatures in layers below the surface of the skin. In the past, those temperatures were most often calculated based on surface temperature measurements using Monte Carlo-type heat flow analyses and temperature estimates. Alternatively, thermocouple probes can now be inserted under the skin in an attempt to measure the real time temperature rise in deeper tissue. Since determining the proper treatment interval is not trivial and the bulk of Altshuler’s suggested treatment time is

far longer than would be appropriate (up to two hours), it is my opinion that the treatment time interval recited in claim 15 is not obvious in view of Altshuler.” (Alexiades Supplemental Declaration ¶17)

In view of the above, it is respectfully submitted that the cited prior art fails to support a prima facie case of obviousness. The latter conclusion is fully supported by the two declarations of Dr. Alexiades. In particular, Anderson fails to teach skin tightening with a broadband spectrum of light. Anderson fails to teach a treatment time. The scattershot teachings in Altshuler ‘3042 of multiple wavelength ranges coupled with dozens of possible treatments is merely an invitation to experiment. Altshuler ‘3042 fails to teach the wavelength ranges claimed by Applicants for any treatment much less skin tightening. Altshuler ‘3042 also fails to teach or suggest the optimum treatment time of 1.2 to 5 seconds.

For the reasons set forth above, it is respectfully submitted that pending claim 15 defines patentable subject matter and allowance thereof, along with the claims depending therefrom, is respectfully requested.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 658312001000**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 11, 2010

Respectfully submitted,

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